

Effect of an Iron Chelator on Microalbuminuria in Diabetic Patients

| | Initial | n | 9M | n |
|--------------------------------|------------|----|------------|----|
| Weight kg | 65.11±2.03 | 28 | 66.33±1.96 | 30 |
| Hemoglobin g/dL | 12.78±0.01 | 28 | 11.75±0.12 | 28 |
| WBC 10 ³ /mL | 7282±170 | 28 | 7077±172 | 30 |
| PMNs % | 70±1 | 28 | 73±1 | 30 |
| Platelets x10 ³ /mL | 2.76± 0.09 | 28 | 2.87±0.08 | 30 |
| SGPT U/L | 20±1 | 28 | 22±1 | 30 |
| SGOT U/L | 20±1 | 28 | 23±1 | 30 |
| Total bilirubin mg/dL | 0.90±0.00 | 28 | 0.95±0.03 | 30 |
| Alk.PO ₄ U/L | 99±1 | 28 | 103±1 | 30 |
| HbA1C (%) | 7.31±0.21 | 30 | 8.11±0.35 | 30 |
| Serum iron µg/dL | 111±17 | 30 | 73±5 | 30 |

| microalbuminuria mg albumin/gm creatinine (normal <30; microalbuminuria 30-300) | | | |
|--|-------|----|-----------|
| | Mean | n | P |
| Initial | 96±14 | 30 | |
| 6 Months | 42±15 | 30 | 0.003* |
| 9 Months | 27±8 | 28 | <0.0001** |
| µg albumin/min (normal <20 microalbuminuria 20-200) | | | |
| | Mean | n | P |
| Initial | 78±13 | 30 | |
| 6 Months | 42±16 | 30 | 0.02* |
| 9 Months | 22±7 | 28 | <0.0001** |

The study involved 30 diabetic patients (17 males and 13 females) with a mean age of 51. The diagnosis of diabetes was confirmed by blood glucose measurements and all patients had microalbuminuria. They received usual and customary care for diabetes.

Patients were initiated on deferiprone (50 mg per kg) for a period of nine months.

Exhibit A
US Application No: 10/820,537